



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,054	12/16/1999	DAVID BURTON	990326.ORI	8408

7590 12/18/2002

STEVEN E KAHM ESQ
NIKOLAI MERSEREAU & DIETZ PA
820 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 554023813

EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,054

Applicant(s)

BURTON, DAVID

Examiner

Mark Rademacher

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 16, 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 4. 6) ☐ Other:

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “means for providing power to the mask” recited in claim 3, the “power source lead” recited in claim 4, “a battery attached to the power source lead”, the “telemetry device” recited in claim 5, and “an ear strap having an oxygen saturation sensor applied to the ear of the patient” recited in claim 20 must be shown or the feature(s) canceled from the claim(s). *No new matter should be entered.*

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

The disclosure is objected to because of the following informalities: On page nine (9) in line twenty-seven (27) it appears a space has been omitted between the terms “mask” and “10”; and on page seven (7) in line six (6) the applicant uses reference character “40” to refer to a conductive material, later in lines twenty-two and twenty-three (22 and 23), the applicant uses the same reference character to refer to “conductive electrode paste”.

Appropriate correction is required.

Claim Objections

Claim 19 is objected to because of the following informalities: In line 3 of claim 19 the applicant recites “the cap includes sensor for measuring EEG”. The applicant has omitted an article before the term “sensor for measuring EEG”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 23 -31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the applicant has not given *any* guidance in the disclosure as to what constitutes a thermally sensitive material. Almost any material is “thermally sensitive” to some degree. Moreover, the applicant does not give *any* guidance as to what thermally sensitive material may be coated onto a mask, and how the coating would be accomplished.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3761

Claims 4, 6, 7, 9, 15, 17-19, 22, and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation “a mask interface connector connecting a power source lead” in line 4. However, in lines 6 and 7, the applicant again recites “a mask interface connector”. It is unclear whether the applicant is referring to first and second mask interface connectors or to a single mask interface connector.

In claim 7, the applicant recites “at least one sensor on the perimeter of the mask”. It is unclear whether the applicant is referring to *the* at least one sensor or whether the applicant is reciting an additional sensor because no article (“a” or “the”) precedes the “at least one sensor”.

In claims 17-19, the applicant recites sensors “that are for measuring” EMG or EEG. As the applicant states in the specification, an EMG (electromyograph) is an instrument for measuring muscle contractions, and an EEG (electroencephalograph) is an instrument for measuring brain activity. It is unclear how a sensor “measures” an instrument such as an EEG or an EMG. The applicant should rewrite the claims to clearly define the nature of the measurement for which the sensors are being used.

In claims 6, 9, 15, 17-18, 22, 29-31 the applicant recites limitations that lack sufficient antecedent basis.

In line 3 of claim 6, the applicant recites “the sensors” for which there is insufficient antecedent basis.

In line 3 of claim 9, the applicant recites “the recesses” for which there is insufficient antecedent basis.

Art Unit: 3761

In lines 3 and 4 of claim 15, the applicant recites “the sensor leads on the cap”, which has insufficient antecedent basis. Dependent claim 19 incorporates the antecedent defect of parent claim 15.

In claim 17, line 3, the applicant recites “the chin strap”, which has insufficient antecedent basis. Similarly, in claim 18 the applicant recites “the straps” for which there is insufficient antecedent basis.

In line 3 of claim 22 the applicant recites “the thermal sensors”, which lacks antecedent basis.

In line 3 of claim 29 the applicant recites “the thermally sensitive material portion”, which also lacks sufficient antecedent basis. Similarly, in line 3 of claims 30 and 31 the applicant recites “the thermally sensitive material portion” for which there is insufficient antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States; or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. 102(b)

Claims 1, 2, 6-10, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure in US statutory invention registration no. H1039 to *Tripp, Jr. et al.*

Art Unit: 3761

In FIG 1 and the accompanying discussion, *Tripp, Jr. et al* disclose an oxygen mask having a perimeter for contacting the face of a wearer (or patient). The oxygen mask 106 includes at least one sensor that senses at least one physiological parameter indicating the state of the wearer (transducers 138 or 140 for example), leads in the mask connected to the at least one sensor for the transmission of data (lead wires 123 and 124 for example) and a hose connector on the mask for the attachment of a hose for the delivery of gas, e.g., oxygen (hose clamp-type connector at the junction of the mask and the hose 126 shown, but not numbered in FIG 2).

In claim 2, the applicant claims the mask of claim 1 wherein the means for transmitting data comprises a mask interface connector for connecting the leads in the mask to a cable. *Tripp Jr. et al* disclose that the multiple conductor electrical cable 128 is attached to a multiple pin connector serve to connect the leads to a cable. See FIGS 1 and 2, column 5, lines 2-6. In dependent claim 3, the applicant adds a means for providing power to the mask to operate the sensors.

Claim 6 adds that the mask in claim 1 that the sensors on the mask are selected from the group consisting of "EEG, EMG, ECG, PTT, temperature, surface blood pressure, pulse, blood oxygen level, light, breathing rate, breathing volume, gas flow, nasal air flow, oral air flow, position, activity sensors, mask leakage, mask pressure, eye movement, microphones, gas pressure, patient recycled air detection, patient back gas and movement". *Tripp, Jr., et al* disclose that sensors in the mask include blood oxygen level sensors, pulse rate sensors and a microphone. See column 5 line 62 through column 6, line 9 for example.

Claim 7 adds to the mask defined in claim one the feature that the at least one sensor on the perimeter of the mask makes contact with the skin of the patient. *Tripp, Jr. et al* disclose that

Art Unit: 3761

the sensors comprising transducers 304-308 contact the skin of the wearer. See FIG. 3 and accompanying discussion in column 8, lines 29-44.

Claim 8 adds to claim 7 that the perimeter of the mask has a soft pliable material for contacting the face of the patient. *Tripp, Jr. et al* disclose that the mask includes a flexible interior conforming member 134 that contacts the face of the wearer.

Claim 9 adds to claim 8 the feature that the pliable material has at least one recess with a sensor in the recesses for contacting the skin. *Tripp, Jr. et al* disclose an aperture 120 in which sensor transducers 132 and 134 are located. See FIG 1 and column 5 lines 24-33 for example.

In claim 10 the applicant adds to claim 9 that the mask features leads in the pliable material that are connected to the at least one sensor for power and data connections therewith. FIG 2 of *Tripp, Jr. et al* shows leads located in the pliable material. See, e.g., the leads connected to sensor transducers 226 and 228.

In claim 12 the applicant adds at least one strap attached to the mask to hold the mask in place to the mask defined in claim 1. *Tripp, Jr. et al* disclose adjustable webbing members 108 in FIG 1 that secure the mask to the wearer. See column 4, lines 50-61.

In claim 14 the applicant adds a cap attached to the mask to hold the mask in place to the mask defined in independent claim 1. *Tripp, Jr. et al* also disclose a cap (helmet 102) that attaches to the mask thereby holding the mask in place against the wearers face.

35 U.S.C. 102(e)

Claims 1-3 and 6

Claims 1-3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by the disclosure in US patent no. 6,199,550 to *Wisemann et al*.

Art Unit: 3761

Wisemann et al disclose a self-contained breathing apparatus mask that incorporates a series of physiologic sensors. The mask is connected to bottled air 12 through breathing tube 13. The mask includes a mask body 100 having a sealing rim 50 that accommodates sensors, e.g., carbon monoxide and heart rate/oxygen saturation sensors 20 and 22. See FIG 3 and accompanying discussion in column 5, lines 21-45.

The mask disclosed by *Wisemann et al* includes a mask having a perimeter (mask body 100 and sealing rim 50), at least one sensor (sensor 20 or 22 for example), leads in the mask (see the dotted lines connecting the sensors 20 and 22 to the processor 160 for example), means for transmitting data from the mask (radio transmitter 14 and its associated antenna, which may be attached to the gas source or the mask; see column 13, lines 55-59 for example, and processor transmitter 345), and a hose connector on the mask (the bottom of the mask in FIG 3 includes a hose connector which is also shown in less detail in FIG 1).

Dependent claim 3 adds a means for providing power to the mask to operate the sensors. *Wisemann et al* also disclose a self-contained power source for powering both the sensors and the transmitter/receiver. See column 13, lines 59 and 60.

Although *Tripp, Jr. et al* anticipates dependent claim 6, which specifies that the sensors on the mask are selected from the group consisting of “EEG, EMG, ECG, PTT, temperature, surface blood pressure, pulse, blood oxygen level, light, breathing rate, breathing volume, gas flow, nasal air flow, oral air flow, position, activity sensors, mask leakage, mask pressure, eye movement, microphones, gas pressure, patient recycled air detection, patient back gas and movement”, *Wisemann et al* disclose a mask as recited in claim 1 that also incorporates a number of sensors listed in the grouping recited in claim 6. Specifically, *Wisemann et al* disclose blood

oxygen level and heart rate, i.e., pulse, sensor 22, patient recycled air and patient back gas and multiple position sensors 200 and 205, which monitor the position of the wearer with respect to her environment and therefore the movement of the wearer. See the last paragraph of column 9 through line 20 in column 10. With respect to a blood oxygen level sensor, a pulse oximeter is discussed in detail in the context of FIG 4.

Claim 4

Claims 1 and 4 ^{are} ~~is~~ rejected under 35 U.S.C. 102(e) as being anticipated by the disclosure in US patent no. 5860417 to *Kettl et al.*

Kettl et al also disclose a mask as recited in claim 1 having a perimeter for contacting a wearer, e.g., a patient (See mask 6 in FIG 1), at least one sensor on the mask to sense at least one parameter indicating a state of the patient (microphone 4), leads in the mask connected to the at least one sensor for transmission of data (wires 38), means for transmitting data from the mask (electrical contact means 28) and a hose connector on the mask for attachment of a hose for delivery of gas to the mask (see hose connected to mask 6 shown in FIG 6).

In claim 4 the applicant adds a means for providing power to the mask to operate the sensors that comprises a mask interface connector connecting a power source lead to a lead in the mask for transmitting power to the sensor, and that the means for transmitting data from the mask comprises a mask interface connector for connecting the leads in the mask to a cable.

Kettl et al disclose a means for providing power to the mask (the combination of the electrical cable 48 and electrical plug 46) that comprises a mask interface connector (electrical plug 46) and that the means for transmitting data from the mask comprise a mask interface connector for connecting the leads (contacts 28).

Art Unit: 3761

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure in US patent no. 6,199,550 to *Wisemann et al* in view of the teaching in US patent no. 5,860,417 to *Kettl et al*.

Wisemann et al disclose a mask having a perimeter, at least one sensor on the mask, leads in the mask connected to the at least one sensor, a means for transmitting data from the mask, and specifically telemetry device, and a hose connector on the mask. See FIG 3. Although *Wisemann et al* disclose a power source for the mask and sensors, *Wisemann et al* do not specifically disclose the use of a battery power source.

However, *Kettl et al* teach the use of a battery to supply power to a mask including sensors. See column 8, lines 31-38.

At the time of invention it would have been obvious to one with ordinary skill in the art to modify the mask disclosed by *Wisemann et al* to include a battery power source as taught by *Kettl et al*.

One of ordinary skill would have been motivated to make the modification in order to construct a mask that is operable in environments where a connection to a remote power source is awkward or unavailable.

Claim 11

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures in US patent no. 6,199,550 to *Wisemann et al*, and in US statutory invention registration no. H1039 to *Tripp, Jr. et al* in view of the teaching in US patent no. 3,606,881 to *Woodson*.

Although *Wisemann et al* disclose a mask having a perimeter for contacting the face of a patient, at least one sensor on the mask that makes contact with the skin of the patient to sense at least one parameter indicative of a state of the patient, leads in the mask connected to the at least one sensor for transmission of data, means for transmitting data from the mask and a hose connector on the mask, *Wisemann et al* do not appear to expressly teach that the perimeter of such a mask is made of a soft pliable material.

However, it is well known in the art that it is desirable to form the perimeter of a mask of a flexible material so that the mask comfortably conforms to the face of the wearer. See, e.g., *Tripp, Jr. et al* column 4, lines 53-68.

Similarly, carbon-embedded rubber materials used for electrical contact between a person's skin and a sensing means are well known in the art. For example, the disclosure of *Woodson* teaches a conductive rubber electrode 16 that is composed of an electrically conductive silicon rubber material filled with an electrically conductive substance such as carbon, graphite or silver. See column 2, lines 24-29.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a conductive rubber electrode in the mask disclosed by *Wisemann et al* (as modified by the teaching of *Tripp, Jr. et al*) to achieve the device recited in claim 11.

One of ordinary skill in the art would have been motivated to do employ the conductive rubber electrode taught by *Woodson* in one of the sensors of *Wisemann et al* mask to create reliable electrical contact between the skin of the wearer and the sensor with out the use of irritating gels or the like. See, e.g., *Woodson*, column 1, lines 32-42.

Claims 13 and 15

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure in US statutory invention registration H1039 to *Tripp, Jr. et al* in view of the teaching in the disclosure in US patent no. 5503147 to *Bertheau*.

Although *Tripp, Jr. et al* disclose a mask having a perimeter for contacting the face of a patient, at least one sensor on the mask to sense at least one parameter indicating a state of the patient, leads in the mask connected to the at least one sensor for transmission of data, means for transmitting data from the mask and a hose connector on the mask, *Tripp, Jr. et al* do not expressly disclose that the mask have at least one strap having a sensor wired to the mask.

Bertheau discloses a respiratory mask having straps 16 that include a sensor 84 located on the harness, i.e., strap 16. See FIG 10 for example.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the mask disclosed by *Tripp, Jr. et al* to include straps having sensors wired therein as taught by *Bertheau*.

Regarding claim 15, at least one of the straps 16, which includes sensor 84, disclosed by *Bertheau* comprise a cap, i.e., fits over the head of the wearer rather than the neck or the chin. See, e.g., FIG 1. Moreover, the mask disclosed by *Tripp, Jr. et al* discloses leads from the sensors are interconnected. See FIG 2 of *Tripp, Jr. et al* for example.

Bertheau discloses that the cap includes a sensor 84 attached thereto and delivers an output signal (via leads as is well known in the art; see, e.g., the *Tripp, Jr. et al* disclosure) to a control component.

At the time the invention was made, it would have been obvious of a person of ordinary skill in the art to modify the mask by *Tripp, Jr. et al* to create the mask recited in claim 15.

One of ordinary skill in the art would have been motivated to make these modifications to the mask disclosed by *Tripp, Jr. et al* to monitor the fit of the mask to the wearer. See *Bertheau* column 6, lines 54-66 for example.

Claims 16-19

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the *Tripp Jr. et al* disclosure in view of the *Bertheau* disclosure as applied to claims 13 and 15 above, and further in view of the teaching in US patent no. 6,032,065 to *Brown*.

Tip, Jr. et al in view of *Bertheau* teach a mask including all of the features of the mask recited in claims 13 and 15. However, the combination does not clearly teach a mask having a chin strap including a sensor, as recited in claim 16, a chinstrap including a sensor for “measuring chin EMG”, as recited in claim 17, a head strap having a sensor “for measuring EEG”, as recited in claim 18, or a cap that includes a sensor “for measuring EEG” as recited in claim 19.

Brown teaches a sensor mask that includes EMG sensors and EEG sensors located in the mouth/chin portion of the mask and the head portion of the mask. See FIG 2 for example and the accompanying discussion in column 3, lines 30-47. As seen in FIG 2, the EMG sensor is located

Art Unit: 3761

in the chinstrap and the EEG sensors are located in a head strap, which may also be considered a cap.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the mask taught by *Tripp, Jr. et al* and *Bertheau* to include the EEG and EMG sensors located in straps on the head and chin of the wearer as taught by *Brown*.

One of ordinary skill would have been motivated to do so in order to increase the physiological data collected from the wearer of the mask.

Claim 20

Claim 20 rejected under 35 U.S.C. 103(a) as being unpatentable over disclosures in US statutory invention registration H1039 to *Tripp, Jr. et al* in view of US patent no. 5503147 to *Bertheau* as applied to claim 13 above, and further in view of US patent no. 5673692 to Schulze et al.

The disclosure of *Tripp, Jr. et al* in view of *Bertheau* does not expressly teach an ear strap having an oxygen saturation sensor applied to the ear of the patient.

Schulze et al disclose an oximeter 70 that is applied to the ear of a patient and which may be incorporated into a larger structure such as an earmuff 76. See FIGS 1 and 4 and the accompanying discussion in column 5, lines 51-56.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add a blood oxygen sensor applied to the ear in an ear strap.

One of ordinary skill in the art would have been motivated to make this modification in order to space the oximeter sensor apart from other sensors in the mask thereby preventing the

potential of interference between the sensors, and because it is well known that the ear is an acceptable area on the head of a person to measure blood oxygen levels.

Claims 21-27 and 29-31

Claims 21-17 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure in US patent no. 6,199,550 to *Wisemann et al* in view of the teaching in US patent no. 5,134,995 to *Gruenke et al*. As discussed above, *Wisemann et al* disclose a mask having a perimeter for contacting the face of a patient, at least one sensor on the mask to sense at least one patient parameter, leads in the mask connected to the at least one sensor for transmission of data, means for transmitting data from the mask and a hose connector for attachment of a hose for delivery of gas to the mask. See, e.g., FIGS 1 and 3 of the *Wisemann et al* disclosure.

Although *Wisemann et al* do not expressly disclose a thermal sensor on a portion of the mask that detects changes in temperature on that portion of the mask, *Gruenke et al* disclose the use of thermal sensors, specifically thermistors or thermocouples located proximate the nose or mouth of a patient to detect physiological changes in the patient. See *Gruenke et al* column 23 lines 56-61.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the use of thermal sensors with the mask disclosed by *Wisemann et al*

One of ordinary skill in the art would have been motivated to do so to monitor the breathing functions of the wearer of a mask for example. See *Id.*

With respect to the location of the sensors, their locations, i.e., internal or external of the mask, *Wisemann et al* disclose sensors on both the external surface (e.g., temperature sensor 26) and the internal surface of the mask (e.g., carbon monoxide sensor 30).

Art Unit: 3761

Claim 28

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 6,199,550 to *Wisemann et al* in view of the teaching in US patent no. 5,134,995 to *Gruenke et al.* claim 21 above, and further in view of US patent no. 6357440 to Hansen et al.

Although the *Wisemann et al* and *Gruenke et al* do not expressly teach that the thermally resistive material comprises a coating on the mask, *Hansen et al* teaches such a coating in the context of a pliable respiratory mask. Specifically, coating 115 is a plastic material. Plastic materials are inherently thermally sensitive, i.e., have physical characteristics that change in response to temperature changes. For example, the malleability of many plastics increases as the temperature increases.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add a thermally sensitive coating as taught by *Hansen et al* to the mask taught by *Wisemann et al* and *Gruenke et al*.

One of ordinary skill in the art would have been motivated to do this in order to decrease the bulkiness of the mask and create a continuous surface of "thermally sensitive" material on the mask.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30 am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the

Art Unit: 3761

organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR
December 13, 2002



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700